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BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Application Number: 10/528,460
Filing Date: December 19, 2005
Appellant(s): GOLZ ET AL.

Lisa M. Hemmendinger
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9/4/2007 appealing from the Office action mailed 2/8/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

Examiner is not aware of any related proceedings.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

There are no pending amendments.

(5) Summary of Claimed Subject Matter

The summary of invention contained in the brief is correct.

(6) Grounds of Rejection to be reviewed on Appeal

The Appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

1. Yuasa et al. JBC 2000;275(40):31469-31479.

2. Lanfear et al. US2002/0115176A1.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1) Claims 1, 5-9 stand rejected under 35 U.S.C. 102(b) as being anticipated by Yuasa et al. (JBC 2000;275(40):31469-31479).

Yuasa et al. teach a method of screening for candidate therapeutic agents, comprising: contacting a test compound with a PDE11A polypeptide; detect binding of the compound to PDE11A polypeptide (page 31473, left column, 3rd full paragraph, page 31476, left column, 1st full paragraph and Table II); wherein His-tagged (detectable label) human PDE11A is expressed and cytosolic extract is prepared from COS-7 cells (in vitro cell-free system), incubated with [^{3}H]cGMP or [^{3}H]cAMP (detectable label), and then counted on a scintillation counter, (see page 31470, right column, 4th full paragraph, also page 31473, left column 3rd full paragraph, and Table II); identifying the test compound as PDE11A inhibitors (page 31477, Table II); analyzing tissue-specific expression patterns of human PDE11A to study its physiological role (page 31475, Figs. 4 & 5).

Therefore, the cited reference is deemed to anticipate the instant claims above.

2) Claims 1, 4-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Yuasa et al., in view of Lanfear et al. (US2002/0115176A1).

Yuasa teaches what is above.

Yuasa does not teach that the contacting step is in or at the surface of a cell, the polypeptide is attached to a solid support, the compound is attached to a solid support.

Lanfear teaches a method of identifying agents that affect the activity of PDE11 and/or the expression thereof comprising adding agent in a cell line that expresses PDE11 (see paragraph [0515]), test compound are synthesized on a solid substrate ([0526], lines 6-7), purified PDE11 can also be coated directly onto plates for screening ([0526], lines 11-13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Yuasa by attaching the polypeptide and compound to solid supports because Lanfear teaches the benefit of using solid support for high throughput screening of compounds having suitable binding affinity to the PDE11 ([0526], lines 1-5). One would have been motivated to make the modification because Yuasa et al. specifically described the method of screening for PDE11A inhibitors and Lanfear teach that attachment to solid support makes it possible for high throughput screening, and would reasonably have expected success in view of Yuasa' teaching that analysis of selective inhibitors for PDEs will elucidate new physiological functions of cAMP/cGMP in prostate and testis (end of page 31478), and Lanfear's teaching that inhibitors of PDEs will lead to more effective therapy with fewer side effects [0008]. The adjustment of particular conventional working conditions (e.g., the step of contacting is in or at the surface of a cell) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited reference before him/her.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

(10) Response to Argument:

1) Claims 1, 5-9 are anticipated by Yuasa

Appellants argue that Yuasa does not expressly disclose step (iii) of claim 1 ("identifying the test compound as a candidate therapeutic agent useful in the treatment of a disease selected from the group consisting of disorders of the peripheral and central nervous system, cardiovascular diseases, cancer, liver disease, and genitourinary disease if the test compound binds to said PDE11A polypeptide"), and that "each PDE plays a distinct physiological role in different tissues and cells and may be valuable pharmacological targets." (page 31469, right column, 2nd full paragraph of Yuasa) is merely a generic teaching that does not expressly or inherently link PDE11A to any of the particular disorders recited in independent claim 1.

The Examiner respectfully asserts that the prior art reference of Yuasa teaches all elements of the claimed invention, including identification of candidate agents (see page 31477, Table II), and analysis of the tissue-specific expression patterns of human PDE11A (Figs. 4 & 5 on page 31475) indicate their therapeutic potential in diseases related with different tissues (distinct physiological role in different tissues, see page 31469, right column, 2nd full paragraph, lines 1-3).

Furthermore, a method of screening for candidate therapeutic agents is claimed not a method of treatment of diseases. The prior art reference of Yuasa teaches all steps in the screening method (including contacting; detecting; and identifying). The identified candidate therapeutic agents of Yuasa are shown in page 31477, Table II. There is no description (in the application) of method/steps of administration of the candidate agent to treat the examined species of cardiovascular disease other than merely state that "the human PDE11A is highly

expressed in the following cardiovascular related tissue" see page 58, line 16-21, and Yuasa teaches tissue specific (including heart tissue) expression patterns of PDE11A in Figs. 4 & 5 on page 31475.

2) Claims 1, 4-11 are obvious over Yuasa in view of Lanfear

Appellants argue that Yuasa does not teach or suggest step (iii) of independent claim 1 and Lanfear does not teach or suggest this step.

Examiner respectfully asserts that the prior art reference of Yuasa teaches all elements of the claimed invention, including identification of candidate therapeutic agents (see page 31477, Table II) and analysis of the tissue-specific expression patterns of human PDE11A, and suggests "Analysis of tissue distribution in detail by means of in situ hybridization and immunohistochemical analyses will be informative in revealing the role of this enzyme. Pharmacological analysis using selective inhibitors for this enzyme will elucidate new physiological function …." (see page 31478, end of right column, to page 31479, top of left column). Thus the step (iii) of claim 1 is taught and suggested by Yuasa.

Furthermore, both Yuasa and Lanfear teach a method of identifying agents that affect the activity of PDE11. Lanfear was relied upon for its teachings that inhibitors of PDEs will lead to more effective therapy with fewer side effects [0008], its expressing of PDE11 in cell line, testing compound on a solid substrate, and coating of purified PDE11 onto plates for screening. When all the references are considered together, the claimed invention is rendered obvious.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Bin Shen

B Shen

Date: 10.24.2007

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